UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,964	10/12/2000	Geert Maertens	2551-48	5719

23117 7590 06/17/2003

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/17/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/686,964	MAERTENS ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *25 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36- 78* is/are pending in the application.

4a) Of the above claim(s) *42 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36- 414 and 44- 78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This action is in response to paper #15.

Claims 36- 41 and 44- 78 are under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The chain of priority to the EPO document filed 17 April 1998 is now perfected.

Information Disclosure Statement

A signed and initialed copy of IDS paper #15 is returned with this action.

Objection Withdrawn

The objection to claim 63 is withdrawn.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 76 and 77 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and enablement. The claim rejections are moot in light of the amendment; however, see new rejections below.

Claims 36-41, and 44- 78 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The lack of clarity caused by the phrase "solid phase carrying" in claim 36 was overcome by the amendment.

Rejections Maintained

Claims 44- 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the peptide variations are not clear.

Applicant has amended claims and asserts that the amendments obviate the rejection.

The amendment has been fully considered and not found persuasive.

It is still not clear what the reference point is for the listed amino acids and it is now also not clear because the portion now reads on single amino acid residues. It is not clear if these are mutations, alternate sequences or just amino acid monomers. The claims remain rejected.

Claim Rejections - 35 USC § 102

Claims 36- 41, 50- 77, and new claim 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Seidel (US 6036579).

This rejection is the same as the 102(b) as anticipated by Seidel; however, now with priority perfected, it applies as 102(e). It is noted that this fact was noted in the prior rejection.

Applicant argues that conditions are different between the patent and the claimed invention as disclosed in column 4, that the claimed products are different from the prior art by virtue of their prior treatment, and that Seidel is not contemplating an immunoassay kit carrying on its solid phase an already reduced antigen HCV NS3.

Applicant's arguments have been fully considered and not found persuasive.

Seidel teaches an immunoassay NS3 HCV antigen bound to a solid support and the advantage of using a reducing agent to aid in detection in particular disclosing that antigen with DTT (a reducing agent) to detect anti-HCV antibodies at an earlier time point than without DTT (Example 5). The step at which reducing agent is added and the step of sulphonation/desulphonation are method steps and are not encompassed in the claimed product. The use of fusion protein and type of assay in kit are inherent to the product and obvious to those skilled in the art. There has been no showing that the product claimed by Applicant is any different from the product in the prior art. While Applicant cites a passage in column 4, it is clear from Example 5 that Seidel contemplated an assay using HCV NS3 antigen on a solid support in the presence of reducing agent and that Seidel realized the benefit of using reducing agent allowed for detection of anti-HCV antibodies at an earlier time point.

The rejection of record is maintained for the reasons of record and as further explained in the response to arguments of Applicant.

Claims 36- 41 and 50 – 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Figard.

Applicant's argues that the reference does not teach polyethylene glycol, glycerol, or polyvinyl acetate, and that DTT increases the sensitivity of ability to detect antibody in the assay.

Applicant's arguments have been fully considered and not found persuasive.

The buffer components argued by Applicant (polyethylene glycol glycerol, or polyvinyl acetate) are not in the claims and Figard includes DTT in the assay buffer. While Figard does not teach that specific reason for inclusion of DTT, Figard does recognize the importance of DTT to protect sulfhydryl groups thereby allowing the HCV antigen to retain its characteristic structure (column 4, lines 33- 52). Furthermore, Figard also contemplates the buffer components argued by applicant (polyethylene glycol glycerol, or polyvinyl acetate); however, Figard concludes that ethylene glycol is superior to those buffer components at protecting DTT (column 4, lines 53- 67).

The rejection of record is maintained.

Claims 39 and 44- 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Leroux-Roels.

Applicant's argument that the reference teaches that the antigen taught has T cell stimulating proterties.

Applicant's arguments have been fully considered and not found persuasive.

Leroux-Roels teaches that these T cell epitopes are required for antibody production, and that immunoassays are well known in the art and widely available (page 2).

One of skill in the art would know that the sequence taught by Leroux-Roels would by useful for detecting antibodies because they are epitopes that generate antibodies as taught by Leroux-Roels. The use of HCV NS3 antigens as part of an immunoassay comprising antigen fixed to a solid support and reducing agent are well known in the art as disclosed by Leroux-Roels. The rejection of record is maintained.

New Rejection(s) Based On Amendment

Claims 76 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims fail to further define the invention because they recite a property that is an intended use and it would have been obvious to one skilled in the art at the time of the invention that an immunoassay kit comprising antigen would be used to detect antibodies.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
June 10, 2003

JAMES HOUSEL 6/16/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600